

### **REMARKS**

Claims 1-6, 8, 10-11, and 13-22 are pending in this application, of which claims 1, 10, 13, 18 and 19 have been amended. Claims 7, 9, 12 have been cancelled. No new matter has been added. Based on the foregoing amendments and following remarks, reconsideration and allowance of the application is respectfully requested.

#### **Information Disclosure Statement**

A supplemental information disclosure statement listing references that were cited in related US Patent Application S.N. 10/669,203 is submitted herewith. Applicant respectfully requests consideration of the references cited in the information disclosure statement.

#### **Claim Objections**

Claims 13, 18 and 19 have been amended to correct informality objections raised by the office action, which are believed to be overcome as a result.

#### **Claim Rejections - 35 U.S.C. §102(b)**

Claims 1, 2, 6, 8, 19 and 22 stand rejected under 35 U.S.C. §102(b), as being allegedly anticipated by U.S. Patent No. 5,749,894 ("Engelson"). In order to sustain a rejection under §102(b), each element in the rejected claim must be found, either expressly or inherently, in the cited reference. Applicant respectfully submits that Engelson cannot support the § 102(b) claim rejections, because Engelson does not disclose each and every element recited in these claims, as amended.

Independent claims 1 and 19 have been amended herein to clarify that the delivering of energy is performed using a source that is located outside the body. Engelson does not disclose or teach the heating of a vaso-occlusive device using a **source of energy located**

**outside a body**. Rather, Engelson teaches using a light-emitting device that “*has been introduced into the region just outside the mouth of the aneurysm*” (Col 8, lines 48-51). Thus, the light emitting device in Engelson is located inside of a blood vessel, which is inside the body. (See, e.g., Figs. 10D, 11D and 12C of Engelson).

Engelson teaches the introduction of a vaso-occlusive device and a polymeric composition in the vasculature of a patient, where the polymers may be reformed to a rigid mass by a source of light or heat located inside the blood vessel. However, Engelson does not disclose or teach a method of releasing or activating **bioactive agents** at the treatment site when the vaso-occlusive device is heated, as recited in claim 1 of the present invention.

For at least these reasons, Applicant respectfully submits that independent claims 1 and 19, along with claims 2, 6, 8 and 22 which depend therefrom, are not anticipated by Engelson.

#### Claim Rejections - 35 U.S.C. §103

Claims 3, 10 and 13 stand rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Engelson in view of US Pub 20040215124 (“Yamasaki”). Claim 10 has been amended to incorporate the limitation of claim 12, which has been cancelled.

The Examiner indicated in the office action that, in view of Yamasaki, it would have been obvious to one skilled in the art to deploy the vaso-occlusive device described in Engelson and position the body in a magnetic resonance imaging (MRI) device to apply magnetic field and thereby heat the vaso-occlusive device. Applicant respectfully disagrees.

As discussed above, Engelson does not disclose heating a vaso-occlusive device using a source of energy located outside a body, or releasing or activating bioactive agents at the treatment site when the vaso-occlusive device is heated (Claims 3, 10 and 13). Neither does Yamasaki.

Yamasaki discloses introducing an irritant in serum form into the aneurysm, causing the aneurysm to shrink *“over the course of several days or weeks”* (Yamasaki, paragraph 62 - 66). Although, MRI may be used to cure the irritant in Yamasaki, there is no suggestion or motivation to modify Engelson to achieve the method of the claimed invention. Certainly, Engelson does not suggest why such modification of a MRI use would be desirable, because the Engelson method requires a light-emitting device that *“has been introduced into the region just outside the mouth of the aneurysm”* in order to reform the polymers. Furthermore, there is no suggestion or motivation to modify Engelson in view of Yamasaki to use MRI energy to release or active bioactive agents at the treatment site when the vaso-occlusive device is heated.

For at least these reasons, claims 3, 10 and 13 are believed patentable over the combination of Engelson and Yamasaki.

Claims 4, 17-18 and 20 stand rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Engelson in view of Yamasaki, and further in view of USP 5,853,418 (“Ken”). Applicant respectfully disagrees. Although, Ken states that a stretch-resisting member provided for a vaso-occlusive coil device may “optionally contain modest amounts of iron” (Col. 5, lines 1-2), there is no mention or suggestion in Ken that such “modest amounts of iron” in the stretch-resisting filament are provided in adequate concentration to cause the stretch-resisting filament to act as a heating member if exposed to an external

energy source when the coil is implanted at a treatment site. In particular, there is no mention in Ken that the coil itself contains, or may optionally contain, any amount of iron, despite a detailed description of what materials the coils are made from (Col 4, lines 47-60).

Independent claim 14 and dependent claim 15 stand rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Ken in view of Yamasaki. The office action indicates that it would have been obvious to provide magnetic resonance to the device of Ken to heat the highly conductive material used in vaso-occlusive devices. Applicant respectfully disagrees. Ken discloses releasing a vaso-occlusive coil in the treatment site using a well-known electrolytically severable joint (Col 6, lines 38-62) and, as indicated above, the coil having a stretch resistance member that may optionally contain “modest amounts of iron.” Yamasaki discloses adding an irritant to an aneurysm, where MRI energy may be used to cure such irritant. However, there is no suggestion or motivation to modify Ken to achieve the method of claims 14 and 15. The application of energy in Ken is used to sever the joint that releases the coil from the delivery device into the treatment site, and not to heat the already delivered coil, as recited in claim 14. As discussed above, there is no evidence that the device of Ken comprises sufficient ferrous material to act as a heating member if exposed to MRI energy. Certainly, Ken does not suggest that such use of MRI energy would be effective to heat the device or otherwise desirable.

For at least these reasons, independent claim 14 is believed patentable over the combination of Engelson, Yamasaki and Ken. Dependent claims 4, 15, 17-18 and 20 are also believed patentable over such combination, for at least the same reasons.

Additionally, claims 5 and 21 stand rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Engelson in view of USP 6,740,094 ("Maitland"). Applicant respectfully disagrees. The office action alleges that Engelson discloses the claimed invention except for the energy source comprising an ultrasound device as disclosed in Maitland. Maitland discloses the activation and expansion of a shape memory actuator when heated to remove blockages in a blood vessel, wherein the energy delivered to the actuator may be ultrasounds waves (Col 6, lines 26-57). As discussed above, however, Engelson does not disclose the methods of claims 5 or 21, and there is no suggestion or motivation to use ultrasound waves to reform the polymeric material of Engelson. Further, such modification of Engelson will still not render the methods of claims 5 or 21, where the heating of the vaso-occlusive device is accomplished by ultrasound device coupled to the exterior of the body, and where the heating releases or activate bioactive agents (claim 5) or heats the blood or tissue in the aneurysm (claim 21).

Claim 11 stands rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Engelson in view of Yamasaki and in further view of USP 5,405,322 ("Lennox"). Claim 16 stands rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Ken in view of Yamasaki and in further view of Lennox. Lennox discloses a method for treating an aneurysm by heating the aneurysm wall with an electrical current generated between two electrodes located in a device inserted into the blood vessel (i.e., inside the body) (Col 4 lines 13-30). In contradistinction, the source of energy used in the methods of claims 11 and 16 is located outside the body, with no electrodes placed internally in the blood vessel. None of Engelson, Yamasaki or Ken discloses the claimed invention alone or in combination with Lennox.

Accordingly, Applicant respectfully submits that the cited references, either alone or in combination, do not teach or suggest the presently claimed methods. Further, the cited references do not provide a motivation for using the presently claimed methods, nor do they provide an expectation of success in its use, nor has the Examiner set forth some other source of motivation for such combination. Therefore, Applicant respectfully submits that a prima facie case of obviousness based on the cited references has not been established, and respectfully requests that the Examiner reconsider and withdraw the obviousness rejections.

**CONCLUSION**

In view of the foregoing amendments and remarks, allowance of all remaining claims is respectfully requested. If the Examiner believes that a telephone interview could expedite resolution of any remaining issues, she is encouraged to contact Applicant's undersigned representative at the phone number listed below.

Respectfully submitted,  
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